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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/356,229	12/19/94	NILSSON K	06/87-50439

HM12/0425
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EXAMINER	
NGUYEN, B	
ART UNIT	**PAPER NUMBER**
1641	34

DATE MAILED: 04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/356,229	Nilsson et al
Examiner	**Group Art Unit**
Bao-Thuy L. Nguyen	1641

☒ Responsive to communication(s) filed on *Election & Preliminary amendment 12/17/99* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *22-49* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *22-49* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 08/11/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/356,229 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant's amendments filed 8/13/99, 8/18/99 and 12/17/99 have been entered. Claims 1-21 have been canceled. Claims 22-49 are pending.

Election/Restriction

3. In view of the amendment to the claims, the restriction requirement made in Paper No. 31 is hereby withdrawn.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 23 and 28-30 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims recite a carbohydrate derivative which is a biologically active part of a naturally occurring carbohydrate sequence which binds in a biospecific manner to at least one membrane selected from the group consisting of a protein, a virus and a cell.

This recitation of the carbohydrate derivative is alleged by Applicant to be supported by the specification at page 3, paragraph 2; however, a review of the specification indicates that page 3, paragraph 2 teaches:

> "...As carbohydrate, one can use fragments (oligosaccharides) of the carbohydrate sequences found in glycoproteins or in glycolipids and one can also use smaller fragments of these sequences, i.e. disaccharide, trisaccharide, tetrasaccharide or a pentasaccharide, because this size usually is sufficient for the oligosaccharide to bind a protein, virus or a cell in a biospecific manner..."

The specification teaches, according to this recitation, that carbohydrate derivatives comprise oligosaccharides, disaccharide, trisaccharide, tetrasaccharide or pentasaccharide, it lacks specific recitation that a carbohydrate derivative is a biologically active part of a naturally occurring carbohydrate sequence. Instead, it appears to be teaching that a carbohydrate derivative is the entire oligosaccharide, or disaccharide etc. Not just the biologically active part of a naturally occurring carbohydrate sequence.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 22-43 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (US Patent No. 4,918,009) in view of Attridge et al (WO 90/01166) and Karube (EP 0215669) for reasons of record in the previous office action, paper no. 17.

Response to Arguments

8. Applicant's arguments filed 8/13/99 have been fully considered but are not deemed to be persuasive.

Applicant argues that Nilsson does not teach a method of carbohydrate derivatives synthesis, but rather, a method of selective synthesis of carbohydrates. This argument has been fully considered but is not deemed to be persuasive. Without further explanation by Applicant, it is unclear how selective synthesis of carbohydrates differs from synthesis of carbohydrate derivatives? Further, Nilsson at column 3, lines 45-64 teaches the enzymatic production of an oligosaccharide compound in which a monosaccharide, for example, is cause to react with an acceptor substance which is an O-, N- glycoside consisting of, for example, another

monosaccharide or oligosaccharide, and at least one aglycon. The resulting compound is a carbohydrate or carbohydrate derivative with an aglycon portion bounded in the 1-position. Further, the carbohydrate derivatives taught by Nilsson are seen to be the same with the carbohydrate derivatives of the instant invention because the specification at page 4, second full paragraph teaches, for example:

> '...examples of carbohydrate derivatives are derivatives where the carbohydrate or a derivative or an analog, are modified in the reducing end with an O-, N-, C- or S-glycosidically bound aglycon which can be an aliphatic or an aromatic compound..."

Therefore, the carbohydrate derivatives of Nilsson are seen to be the same with the instant carbohydrate derivatives.

Applicant argues that Nilsson does not mention how diagnostics using the carbohydrates derivatives might be prepared and for what such diagnostics might be used, and that the reference to "novel diagnostics" was no doubt intended simply to teach the direction in which such research in the area was to be carried out in the future.

This argument has been fully considered but is not deemed to be persuasive because Nilsson teaches the same carbohydrates of the instant invention, and Nilsson further teaches coupling the carbohydrates to proteins or lipids or to solid carriers (column 7, line 28) and that these carbohydrate derivatives have been shown to have a higher association constant to lectins than the naturally receptor, and that this may be applied in the field of diagnostics and therapeutics. Clearly, an ordinary skilled artisan would have had a reasonable expectation of success in using the carbohydrates derivatives of Nilsson in diagnostics and blood typing (column

1, line 41 through column 2, line 9). Diagnostics using specific binding partners such as carbohydrates and lectins are well known in the art and are taught by both Nilsson and Attridge, thus the argument that Nilsson does not teach how diagnostics using the carbohydrates derivatives might be prepared and for what such diagnostics might be used is not persuasive. Clearly, Nilsson provides the motivation and specifically teach placing his carbohydrates derivatives in a solid surface and using it in a detection assay (i.e. diagnostics).

Applicant argues that Nilsson does not teach direct monitoring of biomolecular interaction such as the instant claims. This argument has been fully considered, but is not deemed to be persuasive because Attridge teaches this limitation.

Applicant argues that Nilsson does not teach any reason for immobilizing the carbohydrate derivatives on a solid surface and that no function is disclosed for such immobilized compounds. This argument is not persuasive because Nilsson clearly teaches immobilizing the carbohydrate derivative on solid phases (column, 7, line 28), and the use of these carbohydrate derivatives as diagnostics. Clearly, a skilled artisan can see that such immobilized carbohydrate derivatives might be used as diagnostics, as taught by Nilsson. It is maintained that the solid carriers of Nilsson et al is seen to be functionally equivalent to the solid sensors of Attridge et al., i.e. they are both solid surfaces where carbohydrate derivatives might be immobilized.

Applicant argues that Attridge et al does not teach the carbohydrate derivatives of the claimed invention, nor does Attridge et al teach the spacer molecule portion of the claimed invention.

These arguments have been fully considered but are not deemed to be persuasive because the carbohydrate derivatives and spacer molecule have been taught by Nilsson and the Attridge et al reference is cited for the teaching of biosensors. Specifically, that carbohydrates might be immobilized on gold coated biosensors.

Likewise the reference of Karube is cited for its teachings of piezoelectric crystal biosensor which may be used to immobilized carbohydrates.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Allowable Subject Matter

9. Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 44 and 45 define over the prior art of record because the prior art of record fail to disclose a biosensor comprising a surface having a binding group linked to a spacer molecule and to the surface, or a surface having binding group linked to a protein which is linked to the spacer molecule, or a surface having a protein linked to a binding group which is linked to the spacer molecule the spacer molecule is further bound to a carbohydrate derivative, which carbohydrate derivative specifically binds a protein, a virus or a cell in a sample.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy Nguyen whose telephone number is (703) 308-4243. The examiner can usually be reached Monday through Wednesday, from 8:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bao-Thuy Nguyen
Patent Examiner
Art Unit 1641
April 24, 2000